

REMARKS

Claims 1-19 and 21-71 are now pending with claims 1, 16, 17, 18, 19, 23, 24, and 31 in independent form. Claim 19 has been amended. Claims 1-18 and 21-31 remain unchanged. Claims 32-71 have been added. The Examiner indicated that independent claims 16 and 18 and dependent claims 10, 11, 25, 26, 27, and 30 are allowable.

The Examiner rejected claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31, under 35 U.S.C. § 102(e), as being anticipated by Steiner. Steiner has a filing date of April 30, 2001, and an issue date of January 21, 2003. Steiner is not prior art under 35 U.S.C. § 102(e). Enclosed are a Declaration of Graham Smith Under 37 C.F.R. § 1.131 ("Smith Declaration") and a Declaration of Phyllis K. Kristal ("Kristal Declaration"). The Smith Declaration evidences conception of the claimed invention prior to April 30, 2001. The Smith Declaration and the Kristal Declaration evidence diligence from prior to April 30, 2001 to the filing of the above-captioned application ("the '392 application") on November 8, 2001.

Conception is shown at least by the invention disclosure and drawings attached as Exhibit 1 to the Smith Declaration. On page 1, the entries for "date the idea first came to mind" and "date on which the idea was first reduced to writing in whole or in part" were prior to April 30, 2001 and have been redacted. On page 2, the dates next to the signatures of Graham Smith and Karen Drucker were after April 30, 2001 and have been redacted. On the remaining pages, the dates next to the signatures of Graham Smith and Paul Humby were prior to April 30, 2001 and have been redacted. The drawing on page 2 is substantially similar to Figure 1 of the '392 application. The drawings on page 3 and on the unnumbered pages are substantially similar to Figure 2A of the '392 application. The description in the invention disclosure and drawings embodies the invention of at least claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31 of the '392 application, as follows:

- a) With respect to claim 1, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') configured to selectively restrict movement of a flexible member (i.e., the suture) coupled thereto such that after implantation, the

flexible member can be moved through the restrictor in a first direction while, without the aid of an enlarged portion on the flexible member, movement in a second, opposite direction can be restricted.

b) With respect to claim 2, the restrictor is configured to engage the flexible member to selectively restrict movement of the flexible member. With respect to claim 3, the restrictor is configured to engage the flexible member at a substantially arbitrary position along a length of the flexible member. With respect to claim 4, the anchor body defines an opening through which the flexible member can be moved. With respect to claim 5, the restrictor is configured to engage the flexible member to selectively restrict passage of the flexible member through the opening. With respect to claim 6, the restrictor defines at least a part of the opening. With respect to claim 7, the restrictor defines a narrower portion of the opening than another portion of the opening. With respect to claim 8, the restrictor includes a sloped surface configured to compress the flexible member to permit passage of the flexible member through the opening. With respect to claim 9, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the opening.

c) With respect to claim 12, the anchor body includes a pair of legs. With respect to claim 13, the anchor body includes a bone-engaging ridge for retaining the bone anchor in a bone hole. With respect to claim 14, the anchor body is a unitary body. With respect to claim 15, the anchor body includes a post ('B') about which the flexible member is positionable.

d) With respect to claim 17, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') configured to receive a flexible member (i.e., the suture) such that after implantation of the anchor body within bone, the flexible member can be moved through the restrictor while, without the aid of an enlarged portion on the flexible member, subsequent movement of the flexible member can be restricted. With respect to claim 28, the restrictor includes a sloped surface configured to compress

the flexible member to permit passage of the flexible member through the first restrictor. With respect to claim 29, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the restrictor.

e) With respect to claim 19, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') defining a one-way passage configured to pass a suture in a first direction and restrict passage of the suture in a second, opposite direction. With respect to claim 21, the restrictor includes a sloped surface configured to compress the suture to permit passage of the suture through the one-way passage. With respect to claim 22, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the one-way passage.

f) With respect to claim 23, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') defining an opening having a first portion for permitting passage of a member therethrough, and a second portion restricting passage of the member therethrough without the aid of an enlarged portion on the member.

g) With respect to claim 24, the figures on pages 2 and 3 illustrate a method, including placing an anchor in bone, the anchor including a generally stationary restrictor ('A'); moving a flexible member (i.e., the suture) through the restrictor in a first direction (in the direction of the arrows on page 2), and restricting movement of the flexible member through the restrictor in a second, opposite direction (in the direction opposite the arrows on page 2).

h) With respect to claim 31, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone and to selectively restrict movement of a flexible member (i.e., the suture) coupled thereto. The anchor body defines an opening bounded by a sloped wall ('A'). The sloped wall is configured to compress the flexible member to permit passage of the flexible member through the

opening in a first direction. The sloped wall includes a portion configured to engage the flexible member to restrict passage of the flexible member through the opening in a second, opposite direction.

Diligence is shown at least by work on the '392 application performed by Graham Smith, Marie Concemi and Malcolm Wright, employees of Smith & Nephew, Inc. and Phyllis Kristal, John Conroy, and Peter Devlin of Fish & Richardson P.C., the legal representative of Smith & Nephew, Inc. for the '392 application. In a memorandum from Ms. Concemi to Mr. Wright, dated April 17, 2001 (attached as Exhibit 2 to the Smith Declaration), Ms. Concemi requested that Mr. Wright conduct a prior art search based upon Mr. Smith's invention disclosure and drawings. The dates next to the signatures of Graham Smith and Paul Humby were prior to April 30, 2001 and have been redacted. In an e-mail from Mr. Wright to Ms. Concemi dated April 25, 2001 (Exhibit 3 to the Smith Declaration), Mr. Wright confirmed that he started the search. In a memorandum from Mr. Wright to Ms. Concemi, dated May 1, 2001 (Exhibit 4 to the Smith Declaration), Mr. Wright provided the search results to Ms. Concemi.

In a letter from Ms. Concemi to Ms. Kristal, dated May 8, 2001 (Exhibit 5 to the Smith Declaration and Exhibit 1 to the Kristal Declaration), Ms. Concemi requested that Ms. Kristal evaluate Mr. Smith's invention disclosure and drawings for purposes of filing a patent application. Between May 8, 2001 and November 8, 2001, Mr. Conroy requested and received from Mr. Smith additional drawings for the '392 application (Exhibit 6 to the Smith Declaration and Exhibit 2 to the Kristal Declaration). Note that in Exhibit 6 to the Smith Declaration Mr. Conroy's surname is misspelled as "Cony" in some places. In addition, Ms. Kristal requested and Mr. Smith performed a review of a draft of the '392 application (Exhibit 7 to the Smith Declaration and Exhibit 3 to the Kristal Declaration).

Time records from Fish & Richardson P.C. (Exhibit 4 to the Kristal Declaration) dated from May 9, 2001 through November 7, 2001 show time spent for work on, or related to, preparing the '392 application. The time records show multiple entries for each month during

Applicant : Graham Smith
Serial No. : 09/986,392
Filed : November 8, 2001
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Attorney's Docket No.: 00167-441001 / 02-31-0354

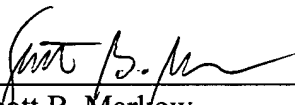
May 2001 through November 2001, evidencing continuous work on the '392 application during this time period.

Therefore, the rejection of claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31, under 35 U.S.C. § 102(e), as being anticipated by Steiner should be withdrawn.

Accordingly, Applicants request allowance of all claims. Enclosed are a \$756.00 check for excess claim fees and a \$950.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 4/1/04



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